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10/552,509	10/05/2005	Noritada Katayama	2005_1546A	2516

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EXAMINER	
SYED, ATIA K	

ART UNIT	PAPER NUMBER
3769	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/552,509	KATAYAMA, NORITADA	
	Examiner	Art Unit	
	ATIA SYED	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9,12,18,22,24,26,28 and 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9, 12, 18, 22, 24, 26 and 28-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *03/23/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges Applicant's response filed on February 3, 2010.

Response to Arguments

Applicant's arguments with respect to claims 9, 12, 18, 22, 24, 26 and 28-29 have been considered but are moot in view of the new ground(s) of rejection.

Note to Applicant Regarding Interpretation of Claim 22

Claim 22 recites that the *measurement calculating unit is configured to determine an abnormality . . . wherein a pulse difference equal to or greater than 7 beats per minute between the pulses measured on the right and left sides of the subject is determined as abnormal by said measurement calculating unit*, which does not necessarily mean that the measurement calculating unit determines abnormality ***only if*** the difference between left and the right pulse rate is equal to or greater than 7 beats per minute. It is Examiner's position that a measurement calculating unit which is configured to make an abnormality determination when the difference between left and the right pulse rate is 1 is sufficient to reject the claim because such a measurement calculating unit would continue making abnormality determination when the pulse difference reaches 2, 3 . . . 6, 7, 8 and even above, i.e. pulse difference equal to or greater than 7 beats per minute between left and right side would be determined as abnormal.

Furthermore, the threshold of difference between the left and right pulse rate is considered a matter of design choice since the Applicant did not provide any specific reason as to why it is important that the threshold be set at 7 beats per minute or more, other than merely

stating that it is ***desirable*** to make abnormality determination at 7 beats per minute or more (specification; paragraph 75).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9, 12, 22, 24 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura et al., US Patent Number 5,724,980 (hereinafter Nakamura) in view of Inagaki et al., US Patent Number 6,344,025 (hereinafter Inagaki) and further in view of Russell, US Patent Number 4,669,458 (hereinafter Russell).

In regards to claim 22, Nakamura discloses a biological information monitoring system comprising:

a plurality of biological information sensor modules adapted to be attached to the right side and left side of a subject body (Nakamura; Fig 1, column 2, lines 44-67 and column 3, lines 1-9.Sensor portion 11a is one sensor module and sensor portion 11b along with processor 2 is a second sensor module),

said biological information sensor modules each incorporating a biological information sensor for detecting biological information (Nakamura; Fig 1, column 2, lines 44-67 and column 3, lines 1-9. The sensors detect blood pressure),

wherein said plurality of biological information sensor modules includes at least a first biological information sensor module and a second biological information sensor module (Nakamura; Fig 1, column 2, lines 44-67 and column 3, lines 1-9.Sensor portion 11a is one sensor module and sensor portion 11b along with processor 2 is a second sensor module),

wherein said first biological information sensor module includes an integrated circuit including a measurement calculating unit configured to determine an abnormality by comparing said biological information detected by said biological information sensor in the first biological information sensor module itself with biological information sent from said second biological information sensor module (Nakamura; Fig 1, column 2, lines 44-67 and column 3, lines 1-9. Sensor portion 11b connected with processor 2 comprises the sensor module with determination means because the processor determines whether the difference between the two blood pressures measurements is over a predetermined value), wherein said biological information detected by said biological information sensor is blood pressure (Nakamura; Fig 1, column 2, lines 44-67 and column 3, lines 1-9. The sensors detect blood pressure).

Nakamura further discloses that the two sensors/blood pressure cuffs send information via a wired connection (Nakamura; Fig. 1).

Nakamura does not disclose that the sensors/blood pressure cuffs include a communicator configured to communicate said biological information by wireless and that the information is sent from one biological information sensor module to another through said communicator.

However Inagaki, a reference in an analogous art discloses a blood pressure monitor where a cuff is provided with transmission and reception portions (equivalent to a communicator) to communicate measured signals wherein the communications are wired or wireless (Inagaki; column 1, lines 60-67 and column 4, lines 35-45). Both references disclose blood pressure cuffs for determining a user's blood pressure.

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Nakamura's blood pressure measuring cuffs that communicate via a wired connection with Inagaki's cuff including transmission and reception portions (equivalent to a communicator) for communicating measured signals wirelessly because Inagaki teaches that a wireless connection improves operability of the blood pressure monitoring device (Inagaki column 2, lines 18-22).

Nakamura as modified Inagaki disclose all limitations of claim 22 except that the first and second sensors are pulse sensors and the measurement calculating unit is configured to determine an abnormality if the pulse difference between the left and the right sides of the subject is equal to or greater than 7 beats per minute.

However, Russell a reference in cardiovascular monitoring art disclose a system for measuring arterial pressure and various heart rhythms (column 8, lines 9-39, wave-form and number or PQRS waves/ minute). The system comprises two sensors attached to the left and the right arm (fig 1A; column 11, lines 19-30) of patient and a computer to analyze the parameters obtained form the sensors (fig 1A and column 11, lines 9-18). The computer issues a warning if the differences between the readings from two sensors fall out of a predetermined range (column 8, lines 9-40 and column 19, line 15 – column 20, line 26). Since the computer or processor is

configured to issue and alarm by comparing the reading from upper and lower limbs, it is sufficient to reject the claim because the threshold of difference between the two readings can be set to any arbitrary number i.e. 1, 2, 3 . . . 7, 8, 9 depending on the user's choice. The threshold of difference between the pulse rate is considered a matter of design choice since the Applicant did not provide any specific reason as to why it is important that the difference be set at 7 beats/minute, other than merely stating that it is ***desirable*** to make abnormality determination at 7 beats per minute or more (specification; paragraph 75).

It would have been obvious to one of ordinary skill in the art to modify the system disclose by Nakamura and Inagaki in view of the heart rate measurement taught by Russell since doing so would provide an added benefit of measuring and comparing pulse rate while measuring blood pressure as taught by Nakamura.

In regards to claim 9, Nakamura discloses a biological information monitoring system set forth in claim 22, wherein at least one of said biological information sensor modules incorporates a memory for storing at least one of the determination result outputted from said measurement calculating unit and the biological information measured by said biological information sensor (Nakamura; Figure 1, processor 2 and display 3 that makes determination and displays the result would inherently have memory).

In regards to claim 12, Nakamura discloses a biological information monitoring system set forth in claim 22, wherein said system further comprises an electronic device for transmitting data to said biological information sensor module by wireless, and wherein said measurement

calculating unit performs abnormality determination with reference to said data sent from said electronic device (Nakamura as modified by Inagaki for the rejection of claim 22 above would have two blood pressure cuffs communicating wirelessly where the processor compares data from both to determine whether the difference between the two blood pressures measurements is over a predetermined value. The cuff without the processor would meet the limitation of an electronic device for transmitting data to said biological information sensor module by wireless, so as to perform abnormality determination with reference to said data sent from said electronic device in said determination means).

In regards to claim 24, Nakamura discloses a biological information monitoring system set forth in claim 22, wherein said plurality of biological information sensor modules further comprises third biological information sensor modules for issuing a warning when said measurement calculating unit detects an abnormality (Nakamura; column 3, lines 10-18, warning).

In regards to claim 26, Nakamura discloses a biological information monitoring system set forth in claim 22, wherein at least one of said biological information sensor modules incorporates a communicator for communicating with the outside to release a determination result of said measurement calculating unit by wireless, and wherein said system comprises an external electronic device for receiving said determination result outputted from said measurement calculating unit (Inagaki figure 3).

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura in view of Inagaki and Russell as applied to claim 26 above and further in view Bessen et al., US Patent Number 5,862,803 (hereinafter Bessen).

In regards to claim 18, Nakamura, Inagaki and Russell do not disclose the biological information monitoring system set forth in claim 26, wherein said communicator transmits identification signals for distinguishing individual living subjects each having the biological information sensor module as well as said determination result data by wireless, to allow said external electronic device to figure out said identification signals and determination result, to thereby identify the individual living subjects.

However Bessen, a reference in an analogous art, discloses a wireless medical diagnosis system with biological sensor modules (Bessen; Abstract and column 13, lines 25-45). Each module is assigned an identification code corresponding to the patient to whom it is attached. An external device can then differentiate between data received from different patients' sensor modules by using the identification code received with the data (Bessen; column 8, lines 5-25). This is equivalent to the claim limitation of wherein said communicator transmits identification signals for distinguishing individual living subjects each having the biological information sensor module as well as said determination result data by wireless, to allow said external electronic device to figure out said identification signals and determination result, to thereby identify the individual living subjects.

It would have been obvious to one of ordinary skill in the art at the time of invention to improve the invention of Nakamura, Inagaki and Russell by using Bessen's technique of having

identification codes for each sensor module corresponding to the patient to whom the sensor module is attached such that the external device receiving data can use the received identification code to differentiate between data from different patients and their sensor modules because it would provide the benefit of preventing confusion between different patients' data and make the device capable of simultaneously serving several patients in a room (Bessen; column 8, lines 5-25).

Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura in view of Inagaki and Russell as applied to claim 22 above and further in view of Sharma, US Patent Publication No. 20030224685 A1 and further in view of Journal of Nursing Science, December 31, 1990 (Hereinafter JNS, provided in IDS).

In regards to claim 28, Nakamura modified in view of Inagaki and Russell in claim 22 would have a processor that compares data from both right and left cuffs to determine whether the difference between the two blood pressures measurements is over a predetermined value and display a warning in that case (Nakamura column 3, lines 1-19). However, Nakamura modified in view of Inagaki and Russell do not disclose that the left and the right sensors are temperature sensors wherein the temperature difference equal to or greater than 0.5 °C between the left and the right side of body is determined abnormal by the measurement calculating unit.

However Sharma, a reference in patient monitoring art disclose a system which includes a plurality of sensors interconnected with different conductive yarns wherein the sensors are mounted on left and the right side of the body. This system is used to measure heart rate, temperature, sweat rate, the physical state of the body, and the like (¶ 80).

It would have been obvious to one or ordinary skill in the art to modify the system as disclosed by Nakamura, Inagaki and Russell in view of the physiological monitoring system taught by Sharma since doing so would result in a system including sensors to measure vital parameters such as temperature, pulse and blood pressure on the left and the right side of the body which provides useful information in determining heart rate and the like (Sharma; ¶ 80).

Nakamura modified in view of Inagaki, Russell and Sharma disclose a system including blood pressure sensors and temperature sensors attached to the left and the right side of the body wherein a measurement calculating unit determines the difference between the left and the right measurement by comparing the readings from the left and right side. However, Nakamura modified in view of Inagaki, Russell and Sharma do not disclose that an abnormality determination would be made if the difference between the left and the right temperature reading is 0.5 degrees C.

However JNS, a reference in an analogous art, discloses that when the temperature difference between the left and right side of a patient was greater than 0.6 degrees C (this meets the limitation not lower than 0.5 degrees C) 9 patients out of 14 died and the remainder had serious problems (*JNS page 2, discussion point 1*).

It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the invention of Nakamura modified in view of Inagaki, Russell and Sharma by switching the temperature different that sets off an alarm from greater than 5 degrees to greater than 0.6 degrees as taught by JNS, because JNS teaches that when the temperature difference between the left and right side of a patient was greater than 0.6 degrees C, 9 patients out of 14 died and the remainder had serious problems (*JNS page 2, discussion point 1*).

Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura in view of Inagaki and Russell as applied to claim 22 above and further in view of *Journal of Brain and Nervous Diseases*, December 31, 1996 (Hereinafter JBND, provided in IDS).

In regards to claim 29, Nakamura modified in view of Inagaki and Russell in claim 22 would have a processor that compares data from both right and left cuffs to determine whether the difference between the two blood pressures measurements is over a predetermined value and display a warning in that case (Nakamura column 3, lines 1-19).

Nakamura, Inagaki and Russell do not disclose a particular number for the predetermined value and therefore do not disclose the limitation wherein a blood pressure difference not less than 10 mmHg between the blood pressures measured on the right and left sides of the subject is determined as abnormal by said measurement calculating unit.

However JBND, a reference in an analogous art, discloses that a difference between the left and right side blood pressures of a patient when greater than 15 mmHg (this meets "not less than 10 mmHg" because it is greater) is of important clinical significance (JBND page 3, lines 1-4).

It would have been obvious to one of ordinary skill in the art at the time of the invention to further modify the invention of Nakamura, Inagaki and Russell to set the predetermined difference value to cause a warning at greater than 15mmHg as taught by JBND, because JBND teaches that a difference between the left and right side blood pressures of a patient when greater than 15 mmHg is of important clinical significance (JBND page 3, lines 1-4).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ATIA SYED whose telephone number is (571)270-7134. The examiner can normally be reached on Monday through Friday, 9:00-5:00 pm, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on (571) 272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ATIA SYED/
Examiner, Art Unit 3769

/Henry M. Johnson, III/
Supervisory Patent Examiner, Art Unit 3769

May 8, 2010